REMARKS

Summary of the Office Action

Claims 1-27 are pending in this application.

Claims 1-27 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Speilvogel et al. (US 5,286,853) in view of Vallana et al. (EP 0 857 470 A2).

Applicant's Response

Applicant respectfully traverses the rejection. In an effort to advance prosecution, however, applicant has amended independent claims 1, 15, 20 to recite that the stable atomic element "emits therapeutic radiation substantially only while being exposed to a thermal neutron irradiation." Neither Speilvogel nor Vallana, either alone or in combination with the other prior art of record, teach or suggest the claimed invention.

Spielvogel discloses a reagent for use in magnetic resonance imaging and neutron capture therapy treatment of cancer, wherein the reagent comprises a suspension of Boron and Gadolinium. As described in Spielvogel, the reagent is injected into the patient days in advance of the radiation therapy so that it is preferentially taken up into the tumor cells (col. 14, lines 6-32). Spielvogel specifically ***teaches away*** from using Gadolinium due to its potential toxicity:

> "gadolinium-157 also has certain disadvantages as a neutron capture agent. The gadolinium complexes are less potent and can be more toxic due to the type of radiation (γ-radiation) generated upon neutron capture. Therefore, a combination of ^{10}B and ^{157}Gd might compensate each isotope's weaknesses and offer a

better therapeutic method of treatment." (Col. 1, lines 38-45)

Spielvogel, therefore, discloses only using a compound that includes Gadolinium and not Gadolinium by itself because of its disadvantages.

Speilvogel also teaches that for treatment of tumor cells, Boron provides short-distance alpha-radiation that is particularly beneficial because the necrotic effects of the radiation are highly localized and preferentially destroy tumor cells. (Col. 7, line 64 to Col. 8, line 14).

Spielvogel plainly ***does not*** disclose a stent for neutron capture therapy, as acknowledged in the Office action. Instead, Spielvogel emphasizes the importance of providing the Boron and Gadolinium in a form that can be excreted from the body (Col. 3, lines 6-9 and 27-32) so as to avoid toxicity effects on normal tissue. Throughout, Spielvogel emphasizes the need to localize the injected Gadolinium in the tumorous cells. There is no suggestion in Speilvogel to use the boron-gadolinium compound disclosed in that patent for a permanently implantable device, much less a stent that contacts systemic blood circulation.

Vallana, on the other hand, teaches a stent fabricated from Tantalum or Iridium. The stent in Vallana is irradiated in a fission reactor ***prior to implantation*** in the patient's body to make it radioactive, emits ***beta-radiation***, and once implanted, does so ***over an extended period of time***. (See col. 3, lines 39-48). Vallana describes that to prevent restenosis, Ta and Ir advantageously have long half-lives, and thus provide continuing action against neointimal formation. (Col. 4, lines 19-20 and FIG. 1). A long half-life is also required for the Vallana stent to have a commercially practicable shelf-life, i.e., it

must remain radioactive between manufacture and eventual implantation.

Vallana does not teach or suggest that restenosis can be prevented using: (1) primarily gamma-radiation, as opposed to beta-radiation released from Ta or Ir; (2) that the stent should or could be irradiated in-situ, as opposed to activated in a fission reactor prior to implantation; or (3) that ***restenosis*** could be prevented using millisecond long bursts of gamma radiation as opposed months-long irradiation with beta particles.

One of ordinary skill in the art of stent manufacture would have learned nothing from Speilvogel that could be applied to the Vallana stent. Spielvogel teaches that Gadolinium provides the "wrong" type of emission when irradiated with a thermal neutron flux, is too toxic, provides emissions that are too short-lived, and could not practicably be used to manufacture the stent of the kind described in Vallana.

In fact, if Gadolinium were to have been incorporated in the Vallana stent, the resulting product would have been inoperative. This is so because the Gadolinium would not have stayed radioactive long enough to activate the stent in a fission reactor, and then implant it in a patient's vessel. Other than hindsight gleaned from applicant's disclosure, there is no teaching or motivation in the prior art to bridge the chasm between the teachings of the prior art and applicant's invention.

Applicant submits that dependent claims 2-14, 16-19, and 21-25 and 27, which depend from independent claims 1, 15, and 20, respectively, patentably distinguish over the prior art of record for at least the same reasons as claims 1, 15, and 20.

CONCLUSION

In view of the foregoing, applicant respectfully submits that the application is in condition for allowance. An early and favorable action is earnestly requested.

Respectfully submitted,

Nicola A. Pisano
Registration No: 34,408
Attorney for Applicant

c/o Luce, Forward,
Hamilton & Scripps, LLP
11988 El Camino Real, Suite 200
San Diego, California 92130
Tel.: 858.720.6320